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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. LIFEWAY FOODS, INC., an Illinois corporation, LFI ENTERPRISES, INC., an Illinois corporation, JULIE SMOLYANSKY, and EDWARD SMOLYANSKY, individuals, Defendants.	)	No. 08-CV-2469 JUDGE ANDERSEN

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, United States of America, by its undersigned attorneys, having commenced this action by filing a Complaint for Permanent Injunction ("Complaint"), and a First Amended Complaint for Permanent Injunction ("Amended Complaint"), and Defendants, Lifeway Foods, Inc. ("Lifeway"), LFI Enterprises, Inc. ("LFI"), Illinois corporations, and Julie Smolyansky and Edward Smolyansky, individuals, (hereinafter, "Defendants"), solely for the purpose of settlement of this case, having appeared and consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest, without admitting or denying liability, and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Amended Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399 ("the Act").

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3. The Amended Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4), and misbranded within the meaning of 21 U.S.C. §§ 343(q)(2)(A), 343(w)(1), 343(*i*)(2), and 343(a)(1).

4. The Amended Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), and misbranded within the meaning of 21 U.S.C. §§ 343(q)(2)(A), 343(w)(1), 343(*i*)(2), and 343(a)(1), while such articles are held for sale after shipment in interstate commerce.

5. Defendants and each and all of their officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them who receive notice of this Decree, are hereby permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a) and the inherent equitable power of this Court, from processing, packing, holding, labeling, and/or distributing at their facilities located at 5201 Harbison Avenue, Philadelphia, Pennsylvania ("Philadelphia facility") and 7625 Austin Avenue, Skokie, Illinois ("Skokie facility"), or any other location, any products labeled as cream cheeses or cream cheese spreads (hereinafter collectively referred to as "cream cheese spreads"), including plain, lite, flavored, or seafood-containing cream cheese spreads, or other seafood products, unless and until:

A. For seafood-containing cream cheese spreads and other seafood products:

i. Defendants select an expert(s) having no personal or financial ties to Defendants or Defendants' families (other than the consulting agreement) and who, by reason of background, experience, and education, is qualified to develop a seafood Hazard Analysis Critical Control Point ("HACCP") plan, and to ensure adequate implementation of such HACCP plan for the processing, packing, holding, labeling, and/or distributing of Defendants' seafood-containing cream cheese spreads and other seafood products at their facilities ("HACCP expert(s)"). Defendants shall inform the United States Food and Drug Administration ("FDA")

in writing of the name(s) and qualifications of the HACCP expert(s) as soon as they retain such expert(s);

ii. The HACCP expert(s) conducts a hazard analysis and develops a HACCP plan(s) that is appropriate for processing, packing, holding, labeling, and/or distributing Defendants' seafood-containing cream cheese spreads and other seafood products;

iii. FDA approves, in writing, the HACCP plan(s) developed by the HACCP expert(s); and

iv. Defendants establish and implement to FDA's satisfaction the FDA-approved HACCP plan(s). Defendants shall assign the responsibility for implementing and monitoring the HACCP(s) plan to an employee or employees trained in HACCP requirements.

B. For plain, lite, flavored, and seafood-containing cream cheese spreads:

i. Defendants select an expert(s) having no personal or financial ties to Defendants or Defendants' families (other than the consulting agreement) who, by reason of background, experience, and education, is qualified to determine whether Defendants' plain, lite, flavored, and seafood-containing cream cheese spreads comply with 21 U.S.C. _ 343 and applicable regulations ("labeling expert(s)"). Defendants shall inform FDA in writing of the name(s) and qualifications of the labeling expert(s) as soon as they retain such expert(s);

ii. Defendants' labeling expert(s) reviews all labels and labeling used by Defendants for their plain, lite, flavored, and seafood-containing cream cheeses spreads, and certifies in writing to FDA that all such labels and labeling are in compliance with 21 U.S.C. _ 343 and applicable regulations; and

iii. Defendants provide to FDA the written certification from the labeling expert(s), and report in writing to FDA, all actions they have taken to ensure that the labels and labeling for their plain, lite, flavored, and seafood-containing cream cheese spreads are in compliance with 21 U.S.C. _ 343 and applicable regulations.

C. Defendants, under FDA supervision, according to procedures approved by FDA, and as and when directed by FDA, bring into compliance with the Act and applicable

regulations to the satisfaction of FDA, all plain, lite, flavored, and seafood-containing cream cheese spreads and other seafood products, held in the Philadelphia facility or Skokie facility, or held elsewhere for distribution by Defendants. Defendants shall provide the formulation of their products to FDA, and at FDA's discretion, Defendants shall perform or have performed for them analytical testing for the presence and quantity of nutrients declared in product labels and/or labeling.

D. FDA, at its discretion, inspects Defendants' facilities, food products, and labeling, including all records and test results relating to the processing, packing, holding, labeling, and/or distributing of plain, lite, flavored, and seafood-containing cream cheese spreads and other seafood products and, as FDA deems necessary, samples and analyzes Defendants' plain, lite, flavored, and seafood-containing cream cheese spreads and other seafood products. The costs of all such inspections and analyses shall be borne by Defendants at the rates specified in Paragraph 10.

E. FDA notifies Defendants, in writing, that they appear to be in compliance with all of the requirements of Paragraph 5(A)-(C), the Act, and applicable regulations.

6. After Defendants receive written notification from FDA as specified in Paragraph 5(E) above, Defendants and each and all of their officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree, are permanently restrained and enjoined from:

A. Directly or indirectly introducing or delivering for introduction into interstate commerce any food within the meaning of 21 U.S.C. § 321(f) that is adulterated within the meaning of 21 U.S.C. § 342(a)(4), or misbranded within the meaning of 21 U.S.C. § 343;

B. Directly or indirectly causing any food within the meaning of 21 U.S.C. § 321(f) to become adulterated, within the meaning of 21 U.S.C. § 342(a)(4), or misbranded within the meaning of 21 U.S.C. § 343, while such food is held for sale after shipment in interstate commerce; and

C. Failing to implement and continuously maintain the requirements of this Decree.

7. Representatives from FDA shall be permitted, without prior notice, and as and when FDA deems necessary, to make inspections of Defendants' facilities at their current locations, or at any future location(s), and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. Such inspections may, at FDA's discretion, include, but are not limited to, the taking of photographs and samples and the examination and copying of all records that relate to the processing, packing, holding, labeling, and/or distribution of any article of food. Such inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

8. Defendants shall maintain copies of their HACCP plan(s) and all records required under such HACCP plan(s) pursuant to 21 C.F.R. Part 123, at the facility specified in such plan(s), in a location where they are readily available for reference and inspection by FDA representatives. Defendants shall retain all records required to be kept by the HACCP plan(s), by regulation, and/or this Decree for at least five (5) years after the date the records are prepared.

9. Defendants shall immediately provide any information or records to FDA, upon request, regarding the processing, packing, holding, labeling, and/or distribution of any article of food.

10. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $81.61 per hour and fraction thereof per representative for inspection work; $97.81 per hour or fraction thereof per representative for analytical or review work; $0.505 per mile for travel expenses by automobile; government rate

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or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day, per representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of Court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

11. If any Defendant violates this Decree and is thus found in civil or criminal contempt, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees (including overhead), investigational expenses, expert witness fees, court costs, and all other costs relating to such contemp proceedings.

12. Defendants shall immediately cease processing, packing, holding, labeling, and/or distributing any plain, lite, flavored, and seafood-containing cream cheese spread or other seafood product, if, based on the results of an inspection, analysis of a sample or samples, or other information, FDA notifies Defendants in writing that such article of food is adulterated or misbranded or that Defendants are not in compliance with the terms of this Decree, the Act, or applicable regulations. In addition, Defendants shall, as and when FDA deems necessary, recall all adulterated or misbranded articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers. In addition, Defendants shall institute or re-implement any of the requirements set forth in this Decree and take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, and applicable regulations. Defendants shall immediately and fully comply with the terms of the notice from FDA requiring them to take corrective actions pursuant to this Paragraph. The provisions of this Paragraph are separate and apart from, and in addition to, all other remedies available to FDA. All costs of recall(s) and corrective actions shall be borne by Defendants. The costs of FDA inspections, sampling, analyses, travel time, and subsistence expenses to implement the remedies set forth in this Paragraph shall be borne by Defendants at the rates specified in Paragraph 10.

13. Any cessation of operations as described in Paragraph 12 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Act, applicable regulations, and this Decree, and that Defendants may resume operations.

14. FDA, at its discretion, may require Defendants to perform or have performed for them, analytical testing of any new or reformulated plain, lite, or flavored cream cheese spread, and any new or reformulated seafood-containing cream cheese spread or seafood product, for the presence and quantity of nutrients declared in product labels and/or labeling. The entity conducting such analyses shall simultaneously provide to FDA and Defendants the results of all tests performed on the samples, along with the labels and labeling that correspond to each sample analyzed.

15. Defendants shall notify FDA, in writing, at least thirty (30) calendar days before any change in ownership, name, or character of the business that occurs after the entry of this Decree, including: a reorganization, relocation, dissolution, assignment, lease, or sale resulting in the emergence of a successor entity or corporation; the creation or dissolution of subsidiaries or any other change in the corporate structure or identity of Lifeway Foods, Inc., LFI Enterprises, Inc., or any other current or future food processing business of Defendants; or the sale or assignment of business assets, such as buildings, equipment, or inventory that may affect compliance obligations arising out of this Decree. Defendants shall serve a copy of this Decree on any prospective successor or assignee at least thirty (30) calendar days prior to such sale or change of business. Defendants shall provide FDA an affidavit of compliance with this Paragraph within fifteen (15) calendar days after such service on a prospective successor or assignee.

16. Defendants shall submit all notifications, correspondence, and communications to FDA required by the terms of this Decree to the Director, FDA Philadelphia District Office, U.S. Customhouse, Room 900, 2nd & Chestnut St., Philadelphia, PA 19106, and

to the Director, FDA Chicago District Office, 550 W. Jackson Blvd., Suite 1500 South, Chicago, IL 60661.

17. All decisions specified in this Decree shall be vested in the sole discretion of FDA. When contested by Defendants, FDA's decisions shall be reviewed, if necessary, by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A) and shall be based exclusively upon the written record that was before FDA at the time of the decision. No discovery may be had by either party.

18. Within ten (10) calendar days after the entry of this Decree, Defendants shall provide a copy of the Decree, by personal service or by certified mail, return receipt requested, to each and all of Defendants' officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them.

19. Within twenty (20) calendar days after entry of this Decree, Defendants shall provide the Directors at both the FDA Philadelphia District Office and Chicago District Office, at the addresses set forth in Paragraph 16, an affidavit of compliance stating the fact and manner of compliance with Paragraph 18, and identifying the names and positions of all persons who were so notified.

20. Within ten (10) calendar days after the entry of this Decree, Defendants shall post a copy of this Decree on a bulletin board in the employee common areas at Defendants' facilities and shall ensure that the Decree remains posted so long as the Decree remains in effect.

21. After entry of the Decree, Defendants shall, within ten (10) calendar days of employment of any new employee hired by Defendants, provide such employee a copy of the Decree, by personal service or by certified mail, return receipt requested. Defendants shall keep these records under this Decree as required under Paragraph 8.

22. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

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ENTER:

WAYNE R. ANDERSEN
United States District Judge

Dated this 15 day of May, 2008.

We hereby consent to the entry of the foregoing Decree.

FOR DEFENDANTS

Dated: May 14, 2008

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Dated: May 14, 2008

Julie Smolyansky
Individually and as President and CEO of Lifeway Foods, Inc. and as President of LFI Enterprises, Inc.

Dated: May 14, 2008

Edward Smolyansky
Individually and as Chief Financial Officer of Lifeway Foods, Inc. and as Chief Financial Officer and Treasurer of LFI Enterprises, Inc.

ENTER:

WAYNE R. ANDERSEN
United States District Judge

Dated this _____ day of _____, 2008.

We hereby consent to the entry of the foregoing Decree.

FOR DEFENDANTS

Dated: May ____, 2008

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Dated: May 14, 2008

Julie Smolyansky
Individually and as President and CEO of Lifeway Foods, Inc. and as President of LFI Enterprises, Inc.

Dated: May 14, 2008

Edward Smolyansky
Individually and as Chief Financial Officer of Lifeway Foods, Inc. and as Chief Financial Officer and Treasurer of LFI Enterprises, Inc.

	FOR PLAINTIFF
Dated: May ____, 2008 Washington, DC	GREGORY G. KATSAS Acting Assistant Attorney General Civil Division U.S. Department of Justice
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